

REMARKS

This Submission is responsive to the Office Action mailed May 19, 2001. Claims 1-16 are pending in the application.

Claims 3, 4, 8-10, and 16 have been canceled without prejudice. Claims 1, 7 and 14 have been amended as discussed below. Claims 5 and 6 were amended to depend from claim 1. Claim 11 was amended to depend from claim 7. No new matter has been added.

REJECTION UNDER 35 USC 102(e)

At page 2 of the Office Action mailed May 19, 2009, the Examiner maintained the rejection of claims 1-3, 6-8 and 13-15 under 35 USC 102(e) as anticipated by Daniell (U.S. Patent 7,129,391) (the '391 patent") filed May 15, 1998) for the reasons set forth in the Office Action mailed October 9, 2008.

Applicants again traverse this rejection. However, solely to expedite prosecution, the claims have been amended without prejudice or disclaimer as follows.

Claim 1 has been amended without prejudice or disclaimer to add that the fertile transplastomic leguminous plant comprises at least one expression cassette inserted into the plastome intergenic region located between the TrnV gene and the rps 12/7 operon. Support for this amendment can be found in throughout the specification and in particular at page 6, lines 10-13 and claim 4. Claims 5 and 6 depend from claim 1, and are also amended by the amendment to claim 1.

Claim 7 has been amended without prejudice or disclaimer to add that one of the two homologous sequences of the transformation vector comprises the genes encoding 16S ribosomal RNA (16SrRNA) and the Valine transfer RNA (TrnV), and the other homologous sequence comprises the intergenic region located between the TrnV gene and the rps12/7 operon. Support for this amendment can be found throughout the specification and in particular at page 5, last line to page 6, line 8, and claim 10. Claims 11-13 depend from claim 7 and are also amended by the amendment to claim 7.

Claim 14 has been amended without prejudice or disclaimer 7 to add that the vector suitable for plastid transformation comprises at least two sequences homologous with a zone of the plastome of the leguminous plant to be transformed, the homologous sequences bordering at least one expression cassette, and wherein one of the two homologous sequences comprises the genes encoding 16S ribosomal RNA (16SrRNA) and the Valine transfer RNA (TrnV), and the other homologous sequence comprises the intergenic region located between the TrnV gene and the rps12/7 operon. Support for this amendment can be found throughout the specification and in particular at page 5, last line to page 6, line 8, and claims 7 and 10. Claim 15 depends from claim 14 and is also amended by the amendment to claim 14.

The amended claims recite the subject matter of claims 4 and 10, which were not rejected as anticipated by the '391 patent. Amended claims 1, 2, 5-7, and 11-15 are not anticipated by the '391 patent. The '391 patent does not disclose the transplastomic leguminous plants, transformation vectors or methods of amended claims 1, 2, 5-7, and 11-15.

Withdrawal of this section 102(e) rejection is again respectfully requested.

REJECTION UNDER 35 USC 103

At pages 4-7 of the Office Action mailed May 19, 2010, the Examiner maintained the rejection of claims 1-16 under 35 USC 103 as obvious over Maliga et al. (U.S. Patent 5,877,402; the '402 patent) in view of von Allmen (GenBank Accession No. X7675) for the reasons set forth in the Office Action mailed October 9, 2008.

Applicants again traverse this rejection. The claims were amended as discussed above.

Maliga et al., U.S. Patent 5,877,402, discloses DNA constructs for transformation of plastids of multicellular plants and expression of foreign proteins in plastids. The DNA constructs comprise a transforming DNA which is targeted to a pre-determined location on the plastid genome and inserted into the plastid genome by homologous recombination with targeting segments comprising DNA sequences homologous to the predetermined region of the plastid genome. Maliga et al. discloses plastid transformation in tobacco using DNA constructs

in which the targeting sequences were tobacco plastid genome sequences. Maliga et al. mentions insertion sites for the targeting segments at column 22, including sites between the *rbcL* and *accD* genes, the inverted repeat region between the *TrnV* and 16S rDNA genes, and the inverted repeat region between the *trnV* gene and the *rps 12/7* operon.

von Allmen, GenBank Accession No. X7675, discloses soybean plastid DNA for *rps12*, *rps7*, 16s rRNA, tRNA-Val, NADH dehydrogenase and ORF 143.

In the present Office Action, the Examiner indicated that Applicants' arguments regarding application of transplastomic technology to plants other than tobacco were not persuasive because at no place does Maliga et al. say that it is not possible to transform soybean or any other legume. The Examiner also indicated that Applicants' remarks that, prior to the present application, no one had obtained fertile transplastomic leguminous plants, was not persuasive because the Daniell '391 patent claimed stably transformed transplastomic leguminous plants.

Applicants respectfully disagree with the Examiner. In order for the Examiner to establish that the claims are obvious, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings, and there must be a reasonable expectation of success in doing so.

Prior to the present application, there were no reports of fertile transplastomic leguminous plants, despite attempts by Zhang et al. and attempts by Daniell in the '391 patent, which Dr. Daniell implicitly admitted were non-enabling in his later publication Daniell et al. (2005), previously submitted for the Examiner's consideration in connection with this application. Even though the '391 patent contains claims to stably transformed transplastomic soybean, peanut and pea plants that contain the universal integration and expression vector disclosed therein, the '391 patent contains no examples where fertile transplastomic soybean, peanut or pea plants were obtained.

At the time of filing of the present application, it was recognized in the art that application of transplastomic technology to plants other than tobacco was hindered by limitations in transformation protocols and tissue culture systems. In addition to Maliga et al., Dufourmantel et al., Zhang et al., Bock et al. and Daniell et al. (2005), all of record in the present application, attributed the difficulties in producing transplastomic plants to technical difficulties, summarized in relation to leguminous plants by Zhang et al.:

It is apparent that many obstacles need to be overcome such as a limited choice of regenerable target tissues and selectable markers, a low frequency of transformation, the poor regeneration of embryogenic tissue, and possible improvement of vector design and delivery, before plastid transformation technology can be readily applied to soybeans.
(Page 42, left column, second full paragraph)

Applicants do not have to show that it was not possible to transform soybean or any other type of legume as alleged by the Examiner. Applicants only have to show that there was no reasonable expectation of success of obtaining the claimed fertile transplastomic leguminous plants in view of the combined teachings of Maliga et al. and von Allmen. The absence of methods that could be used to produce fertile transplastomic plants was recognized in the art to be a problem, not only for leguminous plants, but also for every other species of plant except for tobacco. The state of the art when the present application was filed clearly shows there was no reasonable expectation of producing fertile transplastomic leguminous plants.

In view of the failure of others skilled in the art to produce fertile transplastomic leguminous plants, and the art-recognized obstacles to producing fertile transplastomic plants, except for tobacco, there was no reasonable expectation that fertile transplastomic leguminous plants could be obtained.

Claims 1, 2, 5-7, and 11-15 are not obvious in view of Maliga et al. ('402 patent) and von Allmen. Withdrawal of this section 103 rejection is again respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is respectfully requested and an early Notice of Allowance is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 05500-00148-US. A duplicate copy of this paper is enclosed.

Dated: June 18, 2010

Respectfully submitted,

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